

**Guam - Medicaid Drug Rebate Program (MDRP)**

1115 Waiver Demonstration Application *(Draft)*

Guam - Medicaid Drug Rebate Program (GU-MDRP) 1115 Waiver Demonstration

August 1, 2022

Guam - Department of Public Health and Social Services  
Medicaid Drug Rebate Section 1115 Waiver Demonstration Application

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## SECTION I. NARRATIVE SUMMARY OF THE 1115 WAIVER DEMONSTRATION

### A. Introduction and General Background Information on the Medicaid Drug Rebate Program

As stated on the Centers for Medicare & Medicaid Services (CMS) Medicaid site: The Medicaid Drug Rebate Program (MDRP) is a program that includes CMS, state Medicaid agencies, and participating drug manufacturers that helps to offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. All fifty states and the District of Columbia cover prescription drugs under the MDRP, which is authorized by Section 1927 of the Social Security Act.

The MDRP is designed to offset overall costs of prescription drugs under the Medicaid Program by requiring drug manufacturer to enter into, and have in effect, a National Drug Rebate Agreement (NDRA) with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs.

Manufacturers are responsible for paying a rebate on those drugs for which payment was made under the state plan. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the states and the Federal government to offset the overall cost of prescription drugs under the Medicaid Program.

In addition to signing an NDRA, drug manufacturers are required to enter into agreements with two other Federal programs in order to have their drugs covered under Medicaid: a pricing agreement for the Section 340B Drug Pricing Program, administered by the Health Resources and Services Administration, and a master agreement with the Secretary of Veterans Affairs for the Federal Supply Schedule. Guam Medicaid currently has two (2) Federally Qualified Health Centers (FQHC) that participate under the Section 340B Drug Pricing Program: The Northern Regional Health Center (NRHC) and The Southern Regional Health Center (SRHC). The medications dispensed by these two providers are not eligible for the rebate since they in essence have already been discounted under the manufacturer pricing agreement for the Section 340B Drug Pricing Program mentioned above.

On February 1, 2016, the Centers for Medicare & Medicaid Services (CMS) published the "Medicaid Program; Covered Outpatient Drug" Final Rule with Comment Period (CMS-2345-FC) in the Federal Register (81 FR 5170). As part of that final rule with comment period, CMS amended the regulatory definitions of "States" and "United States" to include the U.S. Territories (American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands) beginning April 1, 2017. Inclusion of the territories in the definitions of "States" and "United States" allows Territories to participate in the Medicaid Drug Rebate Program (MDRP). Additionally, we indicated in the "Covered Outpatient Drug" final rule that territories are able to use existing waiver authority under Title XIX of the Social Security Act to elect not to participate in the MDRP, consistent with statutory provisions (81 FR 5170, 5204).

On November 15, 2016, CMS published an interim final rule with comment period that amended the regulatory definitions of "States" and "United States" to include the U.S. territories beginning April 1, 2020, rather than April 1, 2017 (interim final rule). However, on November 21, 2019, CMS issued "Medicaid Program; Covered Outpatient Drug; Further Delay of Inclusion of Territories in the Definitions of States and United States" Interim Final Rule with comment period that further delayed the inclusion of the U.S. territories (American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands) in the definitions of "States" and "United States" from April 1, 2020 until April 1, 2022. Then on November 19, 2021, the inclusion was delayed mainly due to the public health emergency until January 1, 2023. Because of the inclusion of territories in the definition of States and United States, Guam will be required to

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participate in the MDRP effective January 1, 2023. However, Guam is allowed to use the 1115 waiver authority to elect not to participate in the MDRP.

#### B. Application Request and Rationale for Proposed 1115 Waiver Demonstration

The CMS final rule (CMS-2345-FC) allows the territories to “opt out under...section 1902(j) of the Act.” It is through this waiver authority, that the Guam Medicaid Program is electing to apply under section 1115(a)(1) of the Act to waive section 1902(a)(54) of the Act, which requires state compliance with applicable requirements of section 1927 of the Act that requires Guam Medicaid to participate in the Medicaid Drug Rebate Program (MDRP).

Historically, the Guam Medicaid funding has been limited under the Section 1108 annual block grant, and further limited by the established 55-45% FMAP. These limitations created an environment where the Guam Medicaid Program experienced hesitancy on the part of health care providers on island in participating in the program. The funding increases provided by the Patient Protection and Affordable Care Act (Obamacare) provided a temporary increase in funding, and recent legislation has further provided additional temporary funding and FMAP increases. These increases have helped the Guam Medicaid Program expand services and encouraged provider participation resulting in better recipient access to services that exist today.

Although the Medicaid Drug Rebate Program (MDRP) will offset costs of prescription drugs under the Guam Medicaid Program, the Territory has identified potential negative impacts for pharmacy providers which may ultimately affect the program’s ability to maintain its existing provider network of on-island pharmacies essential for program participants to have adequate access to pharmacy services, and create added labor intensive program costs that may outweigh the benefits of participation in the MDRP.

The island Medicaid pharmacy providers often face challenges in obtaining supplies because of the remoteness of Guam’s location relative to supply chains. This often times creates challenges in the form of accepting higher wholesale pricing from distributors when purchasing pharmaceutical drugs, and paying for higher shipping costs because of the need to transport these supplies via air freight due to their inability to stockpile medication when considering drug expiration dates relative to expected sales and supply needs which often causes inventory or availability issues. This often times translates to more expensive costs that is requested as reimbursement for the sale of these medications to program recipients.

Additionally, due to the relatively insignificant total purchase amounts made through pharmaceutical distributors in comparison to the larger pharmacy chains in the mainland U.S., the island pharmacy providers are unable to negotiate for best prices or favorable shipping terms in obtaining medication supplies. Guam’s participation in the MDRP would place added pressures on the island Medicaid pharmacy providers because it would require them to carry all drugs of a participating manufacturer, and for the program to cover them under Medicaid. Currently, almost all drug manufacturers are participating in the MDRP.

Guam Medicaid has managed to control the costs of Pharmacy expenditures because it currently controls their drug formulary which list covered medication under the program. However, participation in the MDRP would require that we cover all drugs of participating manufacturers, and essentially cover all drugs if the waiver application is not approved. This would be a substantial cost to Guam Medicaid. The current drug pricing for the program’s drug formulary is set at the Lowest Wholesale Price (LWP) under Redbook when the formulary is released in January of each calendar year. The program feels that during this waiver demonstration, they would be able to maintain substantial cost savings for their pharmacy expenditures by maintaining a 16% expenditure

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limitation for this category relative to the total expenditures, and will attempt to assess this standard in comparison with other state Medicaid programs that are under the MDRP.

Under this MDRP 1115 Waiver Demonstration application, the program will be able to continue to maintain control of drug coverage, and properly assess island pharmacy impacts, which is important because of potential drug inventory issues faced by the on-island pharmacies due to our remoteness relative to mainland pharmaceutical supply lines. This waiver may prove to be more of a cost savings when compared to potentially having to cover all drugs of manufacturers that enter into a rebate under the MDRP and due to additional labor-intensive costs associated with participation in the MDRP.

### C. Demonstration Goals

The overall goal of the demonstration is to assure the network capacity of on-island pharmacy providers remains consistent with the existing capacity prior to an implementation mandated for program participation in the MDRP in order to provide adequate recipient access to pharmacy services, and to allow time to properly assess potential adverse effects of participation in the MDRP on our island pharmacy providers, program recipients, and additional administrative program costs related to the management of the MDRP that would possibly outweigh any rebate savings.

NOTE: The demonstration only applies to on-island pharmacy services authorized by the Guam Medicaid State Plan.

The 1115 Demonstration application requests to waive participation in the Medicaid Drug Rebate Program (MDRP) as it will be more costly and labor intensive for Guam to participate in the Medicaid Drug Rebate Program (MDRP) than the rebate savings it provides, and may potentially impact provider (pharmacy) participation.

### D. Demonstration Population

This demonstration will affect all Guam Medicaid State Plan Beneficiaries who utilize Medicaid authorized On-Island Pharmacy Providers.

### E. Eligibility

There are no changes to beneficiary eligibility.

### F. Medicaid Delivery System and Covered Benefits

The Territory does not propose any changes to the Medicaid health care delivery system; demonstration enrollees will continue to receive services through the Territory's fee-for-service delivery system. Demonstration enrollees will also continue to receive benefits through the Alternative Benefit Plan; the Territory does not propose any changes to benefits for any Medicaid enrollees.

## II. HYPOTHESIS AND QUESTIONS

The focus of the evaluation will be to elaborate on the unique pricing and geographical challenges of On-Island Pharmacies due to limited supply chains available in obtaining Covered Outpatient Drugs (COD), and how Guam's participation on the MDRP would affect their current status as Pharmacy providers for the program. Additionally, it will attempt to evaluate the possible MDRP cost savings for the Guam Medicaid program in comparison with the identified potential negative impacts for pharmacy providers which may ultimately affect the program's ability to maintain existing provider networks of on-island pharmacies essential for program participant's adequate access for pharmacy services as well as assess additional labor intensive, administrative costs for the program in participating in the MDRP.

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A. Hypothesis and Questions

**Hypothesis:** Guam Medicaid’s participation in the MDRP would adversely affect the On-Island Pharmacies by creating an unreasonable requirement for them to carry all of a participating manufacturer’s COD such that it would be difficult for them to maintain adequate inventory, and to continue as providers on the Medicaid program. Additionally, it would be more costly and labor intensive for Guam to participate in the Medicaid Drug Rebate Program (MDRP), and these costs would outweigh the rebate savings MDRP would provide.

**Questions:**

1. What are the existing supply chains (Pharmaceutical Distributors) available to On-Island Pharmacies due to Guam’s geographical location?
2. What current limitations do On-Island Pharmacies have in dealing with existing supply chains when ordering CODs for dispensing to Medicaid recipients?
3. How would Guam Medicaid’s participation in the MDRP affect the On-Island Pharmacy Providers decision to continue as a provider on the Medicaid program?
4. Would the cost reduction for pharmacy expenditures outweigh the adverse effects of creating inadequate participant access to On-Island Pharmacy Services?
5. What other costs would be involved in Guam Medicaid’s participation in the MDRP, and would these costs outweigh the benefit of the rebate savings to its pharmacy expenditures.

**In light of the statutory MDRP directive, Guam Medicaid is seeking a waiver exempting them from the requirement to participate in the drug rebate program. Guam is requesting that the exemption from participating in the MDRP be effective from January 1, 2023 - December 31, 2027.**

B. Financial Data

**1. Historical Enrollment and Expenditures**

Guam Medicaid program’s historical enrollment figures for fiscal years 2016 to present and corresponding program year total program expenditures and pharmacy expenditures with projections for FY2022 through FY2027.

**Figure 1. Guam Medicaid Program Historical and Projected - Enrollment and Expenditures Data**

Fiscal Year	Enrollment	Total Expenditures	Pharmacy Expenditure	Pharmacy Expenditures %	Pharmacy Expenditures Per Recipient
FY2016	43673	\$95,382,705	\$23,597,926	24.74%	540
FY2017	43476	\$108,609,905	\$22,251,392	20.49%	512
FY2018	43600	\$110,876,286	\$13,945,932	12.58%	320
FY2019	43671	\$149,037,981	\$21,950,084	14.73%	503
FY2020	43238	\$157,256,853	\$19,570,466	12.44%	453
FY2021	45692	\$123,971,992	\$19,821,809	15.99%	434
<b>FY2022</b>	<b>43892</b>	<b>\$124,189,287</b>	<b>\$20,189,602</b>	<b>16.26%</b>	<b>460</b>
FY2023	43990	\$124,445,463	\$20,234,832	16.26%	460
FY2024	44089	\$124,724,257	\$20,280,164	16.26%	460
FY2025	44187	\$125,003,676	\$20,325,598	16.26%	460
FY2026	44286	\$125,283,721	\$20,371,133	16.26%	460
FY2027	44386	\$125,564,394	\$20,416,770	16.26%	460
<b>*Projected Data</b>					
Note: In Guam’s review/analysis of previous FY data, it appears that the data may be skewed due to program numbers being affected by PHE and it’s social and financial impacts on the island community.					
FY2022 data was projected by averaging the amounts from the six (6) previous years. The program data projections for FY2023 through FY2027 was determined by taking an average increase for data that shows a linear growth for FY2017 through FY2019.					

### C. Pharmacy Provider Participation

#### Current Program Year – Pharmacy Provider Data

**FY2022:**        *23 On-Island Pharmacy Providers;*  
                      *2 FQHC Pharmacy Providers;*  
                      *7 – Off-Island Pharmacy Providers*

## SECTION III. METHODOLOGY

The demonstration will employ both quantitative and qualitative design techniques. The quantitative analysis will rely on evaluation of Pharmacy expenditures relative to expected (Brand, Generic and Inflationary percentages) cost savings to measure projected rebates. The qualitative analysis will rely on information gathered through pharmacy surveys.

### A. Evaluation Design

Qualitative methods will be employed to evaluate:

- \* The possible adverse effects to On-Island Pharmacy Providers should Guam participate in the MDRP;
- \* Current limitations for On-Island Pharmacies with existing supply chains when ordering CODs for dispensing to Medicaid recipients; and
- \* How Guam Medicaid's Participation on the MDRP would affect their provider status on the Medicaid program.

Pharmacy surveys will be used for qualitative/quantitative methods.

Quantitative methods will be used to evaluate MDRP rebate savings relative to average program savings nationwide, and the following anticipated program costs for implementation of the MDRP (42 CFR 447.511).

- \* Cost Benefit Analysis to evaluate potential cost savings provided on the MDRP in relation to potential increases in administrative costs to the program due to requirements for contractual services to administer the tracking and reporting of the data for NDCs to the participating drug manufacturers to include an additional State Agency FTE position to be responsible for the MDRP requirements as a whole.
- \* Guam's assessment of the following Costs associated with participation in the MDRP
  1. Cost of contractor to process claims electronically and invoice manufacturer rebates. (Review of small fee-for-service state, to determine costs for claims processing and invoicing via contractor (e.g., Magellan or Change Healthcare Vendors for minimum cost required to invoice manufacturers, run dispute resolution, and collect money etc.).
  2. Costs involved in developing MDRP Participating Manufacturers NDC Drug Formulary Listing and evaluation of feasibility of developing procedures to prior authorize (PA) drugs to ensure the drugs are from participating manufacturers. (Assess cost and additional labor involved in this procedure).
- \* Guam's assessment of costs for Integrating Physician Administered drugs into rebate processes (42 CFR 447.520)

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Cost associated with invoicing all outpatient drugs administered in a clinical setting or emergency department. Provider training regarding HCPCS coding system in these settings for claims to reference National Drug Code (NDC) or assess costs to perform a crosswalk from the HCPCS to the NDC. (Capture additional work and support needed to integrate these claims into the invoicing process for rebates).

- \* Guam's assessment of the Costs associated with requiring Guam to use actual acquisition cost (AAC) + dispensing fee methodology (42 CFR 447.512)

Cost to pay AAC, if MDRP implemented, requiring Guam to survey its pharmacies regarding their acquisition costs in order to determine if using AWP is close to the pharmacies' acquisition costs and therefore can be used as a basis for reimbursement. A survey would also need to be done to ascertain dispensing fee costs of your pharmacies. (Estimates: Possible cost of \$50,000 -100,000 for the acquisition cost survey and another \$50,000-100,000 to do cost of dispensing fee as needed. (RFQs to assess survey costs).

- \* Assessment of the Drug Utilization Review (DUR) – 1927(g) and 42 CFR 456.703

1. RFQ to assess costs to contract a Provider Benefits Manager (PBM), to conduct Prospective Drug Utilization Review processes (PRO-DUR). All PBMs offer PRO-DUR as part of the claims processing, but need to ascertain any additional costs related to those services.

2. Assess feasibility to work with UPIC West, Qlarant in conducting required Retrospective Drug Utilization Reviews (RETRO-DUR). Guam currently working with CMS contractor as part of program integrity reviews to fight fraud, waste and abuse. (Assess any additional cost).

- \* Assessment and cost breakdown of FTE staff required to be responsible for performing duties related to the Medicaid drug rebate system (Medicaid Drug Product, or MDP) Assess cost associated for a state employee at a minimum of 1/2 of an FTE on Guam's Medicaid staff. (Employee to act as point person for all activities regarding the Medicaid drug benefit to include rebate and Drug Utilization Review, and managing the MDRP contract).

- \* **Assessment Note: Guam will work with CMS to determine an evaluation component for assessing health outcomes to review possible data set for evaluation in developing a metrix measurement for health outcomes and its relationship with provider accessibility (Pharmacy - prescription drug benefits).**

#### B. Data Sources

The demonstration evaluation will rely on data in the Guam Medicaid Management Information System (MMIS) otherwise known as PHPro which does Fee-for Service based claims processing. Use of financial program data will be limited to final paid status claims. HHS/CMS, MDRP Participating Manufacturer Rebate data, and other available State Medicaid Enrollment and Expenditure data reported to CMS.

## SECTION IV. COMPLIANCE WITH PUBLIC NOTICE PROCESS

### **Public Notice:**

- \***Publication in the Guam Daily Post, June 20, 2022 (See attached)**

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\*Posting on the Government of Guam, Department of Administration-Public Notice Site ([Public Notices - Public Notices Portal - Government of Guam](#))

\*Posting on the Department of Public Health and Social Services, Division of Public Welfare, Bureau of Health Care Financing Administration, Guam Medicaid site (<http://dphss.guam.gov/category/press-releases-en/>)

**Public Hearings:**

1. June 27, 2022 – Guam Legislative Information Hearing (1-3:00 p.m. CHST) (<https://youtube.com/c/GuamLegislatureMedia>, [\(58119\) Joint Public Hearing - Speaker Therese M. Terlaje - June 27, 2022 1pm - YouTube](#))
2. July 8, 2022 – DPHSS In-Person and Virtual (Zoom) Information Hearing (Governor's Conference Room, Ricardo J. Bordallo Complex, 513 West Marine Corps Drive Hagatna, Guam 96910, 1-3:00 p.m. CHST)

**30 day comment period:** June 20, 2022 to July 28, 2022

1115 Waiver Demonstration Application submitted on **August 1, 2022** (Link to copy of application available at <https://www.dphss.gov...>)

**SECTION V. STATE CONTACT AND SIGNATURE**

State Medicaid Director Name: Teresita C. Gumataotao

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Authorizing Official (Typed): Arthur U. San Agustin, MHR, Director, **Department of Public Health and Social Services**

Authorizing Official (Signature): \_\_\_\_\_

Date: **August 1, 2022**

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Notes:

1115 Waiver Components:

\*A comprehensive program description of the demonstration, including the goals and objectives to be implemented under the demonstration project

\*A description of the proposed health care delivery system, eligibility requirements, benefit coverage and cost sharing (premiums, copayments, and deductibles) required of individuals who will be impacted by the demonstration to the extent such provisions would vary from the state's current program features and the requirements of the Social Security Act

\*An estimate of the expected increase or decrease in annual enrollment, and in annual aggregate expenditures, including historic enrollment or budgetary data, if applicable

\*Current enrollment data, if applicable, and enrollment projections expected over the term of the demonstration for each category of beneficiary whose health care coverage is impacted by the demonstration

\*Other program features that the demonstration would modify in the state's Medicaid program and/or CHIP

\*The specific waiver and expenditure authorities that the state believes to be necessary to authorize the demonstration

\*The research hypotheses that are related to the demonstration's proposed changes, goals, and objectives; a plan for testing the hypotheses in the context of an evaluation; and, if a quantitative evaluation design is feasible, the identification of appropriate evaluation indicators

\*Written documentation of the state's compliance with the public notice requirements, with a report of the issues raised by the public during the comment period, which shall be no less than 30 days, and how the state considered those comments when developing the demonstration application.

- **Guam Medicaid is continuing to work with CMS to meet the required 1115 Waiver Demonstration Application components listed above.**